

Ask the Ethicist: Research Abroad

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Q: *An American ophthalmologist would like to test a novel surgical procedure that includes the use of a new device. The surgeon travels outside the United States and performs the experimental procedure on a large number of patients, bypassing the oversight of domestic institutional review board requirements for protection of human subjects in research. The ophthalmologist intends to subsequently report her findings at a major academic meeting in the United States. Please comment on the ethics of this activity.*

A: The key ethical principle of this inquiry is that, while specific oversight and documentation requirements may differ by country as determined by national law, the mandates of medical ethics for protection of human research subjects do not. Specifically, the essentials of special informed consent for human research—and the specific requirements set forth in detailed international standards for human investigation (the Nuremberg Code and the World Medical Association Declaration of Helsinki)—must be respected regardless of venue.

Academy member investigators also should be aware that the Academy imposes ethical requirements on members who conduct research (Code of Ethics Rule 3). Furthermore, program committees for major academic meetings, including the Academy's Annual Meeting, may require documentation of adequate oversight in order to accept research for presentation. Similarly, if research that involves human subjects is to be submitted for subsequent publication, documentation of approval by the domestic institutional review board will likely be required regardless of where the patients are from or where the study was conducted.

While the research oversight “paper chase” may be more liberal abroad, ophthalmologists must defer to their duties as set forth in our Code of Ethics and international codes.

For more information or to submit a question for this column, contact the Ethics Committee staff at ethics@aao.org. To read the Code of Ethics, visit www.aao.org/about and click “Ethics” and “Code of Ethics.”